

PATENT ABSTRACTS OF JAPAN

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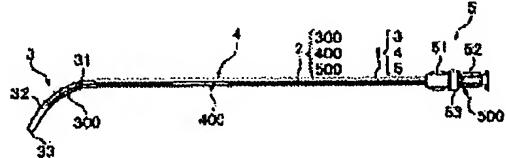
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(54) CATHETER HAVING STYLET

(57)Abstract:

PROBLEM TO BE SOLVED: To provide a catheter having a stylet that can be inserted precisely without straying in a branch vein, in particular, in an ascending main vein (vena cava) in the large calory injection treatment method, without a guiding by a guide wire, and does not damage the vein.

SOLUTION: This is a catheter having a stylet in which a flexible catheter made of a top end part, a main body part, and a base part and a stylet made of a top end part, a main body part, and a base part that is inserted in the lumen of the catheter are engaged at the base part of the catheter and the base part of the stylet. The top end part of the catheter and the top end part of the stylet are bent in accordance with the vein shape at the introduction target portion at nearly the same position and the tip end of the stylet does not protrude from the tip end of the catheter.



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CLAIMS

[Claim(s)]

[Claim 1]A flexible catheter which consists of a tip part, a body part, and a base end, and stylette which consists of a tip part, a body part, and a base end which were inserted in a lumen of this catheter. It is the catheter with the stylette currently engaged in a base end of this catheter, and a base end of this stylette, and a tip part of said catheter and a tip part of said stylette are curving in the almost same position according to blood vessel shape of an introductory target part.

A catheter with the stylette not having projected a tip of said stylette from a tip of said catheter.

[Claim 2]Said catheter is a 4-8-cm position from a tip.

And the catheter with the stylette according to claim 1 provided with the 1st bend that is curving in the almost same position as said stylette, and the 2nd bend that is curving in a position by the side of a tip rather than this 1st bend.

[Claim 3]The catheter with the stylette according to claim 2 with which angle theta₁ of a line by which said 1st bend passes along a body part of said catheter, and a line which passes along the 1st portion of a tip part of said catheter that is a straight line mostly to make is formed so that it may become 30 to 70 degrees.

[Claim 4]The catheter with the stylette according to claim 2 or 3 with which said 2nd bend is curving in a 1-3-cm position from a tip of said catheter.

[Claim 5]The catheter with the stylette according to any one of claims 2 to 4 with which angle theta₂ of a line by which said 2nd bend passes along the 1st portion of a tip part of said catheter it is [portion] a straight line mostly, and a line which passes along the 2nd portion of a tip part of said catheter that is a straight line mostly to make is formed so that it may become 5 to 45 degrees.

[Claim 6]The catheter with the stylette according to any one of claims 2 to 5 currently formed rather than the 1st bend of said catheter so that, as for the tip side, rigidity may become low rather than a body part of said catheter.

[Claim 7]The catheter with the stylette according to any one of claims 1 to 6 in which said catheter is catheterization of vein for intravenous hyperalimentation with which a tip part is detained in superior vena cava.

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention] This invention relates to the catheter which is inserted from a body surface and detained in the inside of the body. It is inserted in the inside of the body especially by a subclavian puncture method, and the tip of a catheter is related with the stylette used for the intravenous hyperalimentation therapy detained in superior vena cava.

[0002]

[Description of the Prior Art] Conventionally, when performing an intravenous hyperalimentation therapy, a central venous catheter is generally detained in superior vena cava. Although the schematic diagram of the blood vessel near superior vena cava (venae centrales hepatis) when the patient has turned to the transverse plane is specifically shown in drawing 7, At such a catheter leaving method, after it carries out the puncture of division type KANYURA which generally has an inner needle by a subclavian vein puncture method and a needle tip reaches a blood vessel, extraction of the inner needle is carried out and the tip of a catheter is detained in the optimum detention region shown in superior vena cava with the slash via above-mentioned KANYURA. When a way person performs blood vessel reservation, in the approach from an internal jugular vein, hardly become a problem, but. In the case of a subclavian vein puncture, there was a problem that there was a risk of carrying out involvement (the poor position of a catheter: mislodging) to the subclavian vein of an opposite hand, etc. depending on the blood vessel arrival position of a needle tip especially with an internal jugular vein, the vena jugularis externa, or a needling position. Here, the blood vessel arrival position of the needle tip which may carry out involvement is carried out [that it is near / like the turning point of a subclavian vein and an internal jugular vein / a tee in many cases, and]. For example, in order to make a site of puncture exaggerate, a patient is made to turn to the left, when a way person does a puncture towards the right subclavian vein as shown in drawing 8, but the right internal jugular vein becomes the arrangement which becomes linear shape from the right subclavian vein at this time. In such a case, the stage where a catheter projects in the case where a straight catheter is inserted, from the tip (side which carried out the puncture to the blood vessel) of division KANYURA if a needle tip reaches near the tee shown by the arrow rather than the optimum puncture region. Before riding the flow of blood and going downward (the direction of superior vena cava), it has become that it is easy to be inserted toward the direction of the right internal jugular vein. Once the tip of blood vessel Hecate Tell thinner than superior vena cava other than superior vena cava carries out involvement, The tip of the catheter became that it is easy to hit a blood vessel wall, or vascular endothelium was stimulated, and there was a problem that the extravasation (Extravasation of Fluids) that the infusion of nutrient of the hypertonicity supplied from a catheter encroaches on the outside of the blood vessel occurred.

[0003] Some trials are made in order to solve the problem of the involvement to blood vessels other than the above-mentioned superior vena cava. For example, by the method of a description, to JP,H8-224312,A. The catheter which inserted the stylette which consists of stranded wires is indicated, this stylette is the structure bent from the tip of the stylette to about ten to 15 bend angles in an about 12-mm position, and the tip of the stylette is located in the nearly tip of a catheter. Although it is indicated by considering it as the shape mentioned above in the gazette that detention to superior vena cava is certainly possible, In near the tee from the subclavian vein which has comparatively big space in such a catheter since the bend is a nearly tip of a catheter as shown in drawing 9 to superior vena cava, Since this catheter rotated in every direction in the stage where a catheter projects from the tip of KANYURA 10 as shown in drawing 10, it was not effective for making it located in an optimum direction. From this, in order to turn the tip of a catheter to the superior-vena-cava side, at the time of insertion, it always needed to take care. therefore -- a way person requires [that the big sense of security about not carrying out involvement of the catheter cannot be obtained, and] skill too -- experience -- the involvement of the catheter may have been started in the unripe resident. Since the stylette is inserted to

the nearly tip of a catheter, when pushing intensity is too strong and the tip of a catheter projects from division KANYURA, for example. Like the case where the tip of the stylette has projected from the tip of the catheter, the tip of the catheter contacted the blood vessel wall and there were problems, like there is a possibility of damaging a blood vessel wall.

[0004]

[Problem(s) to be Solved by the Invention] An object of this invention is to provide the catheter with the stylette which can insert without guidance by a guidewire correctly, without carrying out involvement especially to a branching blood vessel and the superior vena cava in an intravenous hyperalimentation therapy, and does not damage a blood vessel.

[0005]

[Means for Solving the Problem] This invention persons by using a catheter with the stylette which has a specific structure where stylette and a catheter curve by the same part as a result of inquiring wholeheartedly that SUBJECT mentioned above should be solved. It found out safety and that a catheter could be carried forward to a desired position correctly and easily, and resulted in this invention. That is, this invention provides following the (1) - (7) with a catheter with the stylette of a description.

[0006](1) A flexible catheter which consists of a tip part, a body part, and a base end, and stylette which consists of a tip part, a body part, and a base end which were inserted in a lumen of this catheter, Are the catheter with the stylette currently engaged and in a base end of this catheter, and a base end of this stylette a tip part of the above-mentioned catheter, and a tip part of the above-mentioned stylette, A catheter with the stylette curving in the almost same position and not having projected a tip of the above-mentioned stylette from a tip of the above-mentioned catheter according to blood vessel shape of an introductory target part.

[0007](2) A catheter with the stylette given in the above (1) provided with the 1st bend that the above-mentioned catheter is a 4-8-cm position from a tip, and is curving in the almost same position as the above-mentioned stylette, and the 2nd bend that is curving in a position by the side of a tip rather than this 1st bend.

[0008](3) A catheter with the stylette given in the above (2) in which angle theta₁ of a line by which the 1st bend of the above passes along a body part of the above-mentioned catheter, and a line which passes along the 1st portion of a tip part of the above-mentioned catheter that is a straight line mostly to make is formed so that it may become 30 to 70 degrees.

[0009](4) The above (2) in which the 2nd bend of the above is curving in a 1-3-cm position from a tip of the above-mentioned catheter, or a catheter with the stylette given in (3).

[0010](5) The 2nd bend of the above, the above -- a catheter -- a tip part -- almost -- a straight line -- it is -- the -- one -- a portion -- passing -- a line -- the above -- a catheter -- a tip part -- almost -- a straight line -- it is -- the -- two -- a portion -- passing -- a line -- making -- an angle -- theta -- two -- five -- 45 -- a degree -- becoming -- as -- forming -- having -- **** -- the above -- (two) -- (four) -- either -- a description -- the stylette -- with -- a catheter.

[0011](6) A catheter with the stylette given in either of above-mentioned (2) - (5) currently formed rather than the 1st bend of the above-mentioned catheter so that, as for the tip side, rigidity may become low rather than a body part of the above-mentioned catheter.

[0012](7) A catheter with the stylette given in either of above-mentioned (1) - (6) whose above-mentioned catheters are catheterization of vein for intravenous hyperalimentation with which a tip part is detained in superior vena cava.

[0013]

[Embodiment of the Invention] The flexible catheter with which the catheter with the stylette of this invention consists of a tip part, a body part, and a base end, The stylette which consists of the tip part, body part, and base end which were inserted in the lumen of this catheter, It is the catheter with the stylette currently engaged in the base end of this catheter, and the base end of this stylette, The tip part of the above-mentioned catheter and the tip part of the above-mentioned stylette double with the blood vessel shape of an introductory target part, It is curved or crooked in the almost same position (only henceforth a "curve"), and the tip of the above-mentioned stylette is a catheter with the stylette not having projected from the tip of the above-mentioned catheter. Although Drawings are used for below and one suitable example is explained to it in detail about the catheter with the stylette of this invention, the catheter with the stylette of this invention is not limited to this.

[0014] As shown in the whole catheter side view with the stylette of this invention of drawing 1, the catheter 1 comprises the tip part 3, the body part 4, and the base end 5, and is, and the stylette 2 comprises the tip part 300, the body part 400, and the base end 500. As it is indicated in the enlarged drawing of the tip part of drawing 2 and the catheter with the stylette of this invention of drawing 3 as a tip part, here, It is the portion into which the tip side is curving from the 1st bend 31 including the 1st bend 31 where the catheter 1 and the stylette 2

are curving in the almost same position, and a body part is a portion into which the catheter 1 and the stylette 2 are not curving.

[0015]A base end is the portion and this add-on with which add-on (the catheter connector 51, the stylette connector 52, and the lock part 53) sticks to the catheter 1 and the stylette 2, as shown in the enlarged drawing of the base end of the catheter with the stylette of this invention of drawing 4. Specifically, the above-mentioned base end is equipped with the catheter connector 51 which can fix the catheter 1, and the stylette connector 52 which this catheter connector 51 and fitting are possible, and can fix further the stylette 2 inserted in the lumen of the catheter connector 51. It is the above-mentioned stylette connector's 52 having the lock part 53, having a locking mechanism of this lock part 53, and carrying out lock fitting of the catheter connector 51 and the stylette connector 52. Wearing immobilization of the stylette connector 52 is carried out certainly at the catheter connector 51. Therefore, the catheter connector 51 into which male lure can fit with the above-mentioned base end, the stylette connector 52 and the lock part 53, the portion that touches this catheter connector 51 of the catheter 1 further. And it is the thing of a portion which inserts in the lumen of this catheter connector 51 of the stylette 2, and touches the stylette connector 52.

[0016]By providing the lumen which opened from the tip of the stylette connector 52 to the back end for free passage, and connecting a syringe etc. to this back end, the above-mentioned stylette connector 52 is made composition so that passage of a fluid (drug solution) may be attained. It becomes possible to carry out that check which the tip 33 of priming by the physiological saline in a catheter, etc. and the catheter by viewing the back run of blood is contained in the blood vessel, without this extracting the stylette 2 from the catheter 1, or is not contained.

[0017]the 1st bend 31 in the above-mentioned tip part — the tip part 3 of a catheter, the body part 4 of a catheter and the tip part 300 of the stylette and the body part 400 of the stylette, and ***** — it being the bend which is curving in the same position, and, It is more preferred than the tip 33 of a catheter to be formed in the range of 4-8 cm, and it is more preferred to be formed in the range which is 4.5-6 cm. The angle of the line by which the 1st bend 31 of the above passes along the body part 4 of a catheter, and the line which passes along the 1st portion of the tip part 3 of a catheter that is a straight line mostly to make, And so that it may be shown in the angle of the line which passes along the body part 400 of the stylette, and the line which passes along the 1st portion of the tip part 3 of the stylette that is a straight line mostly to make, i.e., drawing 3. If the angle of the dashed line which extended the body part 4 of a catheter and the body part 400 of the stylette, and the dashed line which extended the virtual straight line to which it is not curving from the 1st bend 31 to the 2nd bend 32 to make is made into angle theta₁, It is preferred to be formed so that angle theta₁ may become a range which is 30 to 70 degrees, and it is 40 to 50 degrees still more preferably 35 to 60 degrees more preferably. In the definition of the angle which the account of the upper makes, although the tip part shown in drawing 3 is explained as a structure bent linearly in the 1st bend 31 and 2nd bend 32, the catheter of this invention has structure which curved in the bend like the tip part shown in drawing 2. When it hits a blood vessel wall, it is desirable from the Reason which cannot damage a blood vessel wall easily.

[0018]By making the formation position of the 1st bend 31 of the above, and angle theta₁ form in a mentioned range, When carrying out the puncture of the catheter near the turning point of a subclavian vein and an internal jugular vein constituting the cause of involvement mentioned above, as shown in drawing 5 and 6, since near the tip part of the catheter projected from KANYURA 10 serves as shape which does not go to any blood vessels other than an optimum detention region, it is preferred. Therefore, by making the 1st bend 31 form in the tip part 3 of a catheter, and the tip part 300 of the stylette, Rather than near the tee of a subclavian vein and an internal jugular vein, of course, when the puncture has been carried out near a tee, it becomes possible from the distance by the side of a shoulder to insert direction Hecate Tell of superior vena cava certainly.

[0019]If the formation position of the 1st bend 31 of the above is formed in addition to the mentioned range, a possibility that the tip 33 of a catheter will carry out involvement to the subclavian vein of an opposite hand will arise. When the above-mentioned angle theta₁ is less than 30 degrees, There is a danger that an angle will be too small and the tip 33 of a catheter will be inserted in an internal jugular vein, and when it is more than 70 degrees, When the tip 33 of a catheter is inserted in superior vena cava, the tip 33 of a catheter hits a blood vessel wall easily, and a blood vessel wall may be damaged at the time of catheter implantation.

[0020]Bend-radii rho₁ in the 1st bend 31 of the catheter with the stylette of this investigation, As for bend-radii rho₁ in a bend, since there is a possibility that a bend may become sharp and may stimulate a blood vessel, and the case below 3 mm may not understand anymore well the hand feeling at the time of the catheter implantation which was curving too much and was mentioned above when it is more than 50 mm, it is preferred that it is the range of 3-50 mm.

[0021] As for the above-mentioned catheter 1, in the tip part, the 2nd bend 32 is established in the position by the side of the tip 33 of a catheter from the 1st bend 31 of the above. That is, the catheter with the stylette of this invention has the shape which curved in the 1st bend 31 and 2nd bend 32 in the tip part 3 of a catheter. Here, as for the 2nd bend 32 of the above, it is more preferred than the tip 33 of a catheter to be formed in the range of 1-3 cm, and it is more preferred to be formed in the range which is 1.5 to 2.5 cm. the angle of the line by which the 2nd bend 32 of the above passes along the 1st portion of the tip part 3 of a catheter it is [portion] a straight line mostly, and the line which passes along the 2nd portion of the tip part 3 of a catheter that is a straight line mostly to make, i.e., drawing 3, -- ** -- like, If the angle of the dashed line which extended the virtual straight line to which it is not curving from the 1st bend 31 to the 2nd bend 32, and the dashed line which extended the virtual straight line to which it is not curving from the 2nd bend 32 to the tip 33 of a catheter to make is made into angle theta₂, It is preferred that angle theta₂ is a range which is 5 to 45 degrees, and it is 10 to 30 degrees still more preferably 7 to 40 degrees more preferably. As mentioned above, in the definition of the angle which the account of the upper makes, the tip part shown in drawing 3 is explained as a structure bent linearly in the 1st bend 31 and 2nd bend 32, but the catheter of this invention has structure which curved in the bend like the tip part shown in drawing 2. When it hits a blood vessel wall, it is desirable from the Reason which cannot damage a blood vessel wall easily.

[0022] By making the formation position of the 2nd bend 32 of the above, and angle theta₂ form in a mentioned range, since the detention operation to superior vena cava becomes more certain, it is desirable. Since it may stop saying that the 1st bend 31 is the stage projected from KANYURA, and the tip 33 of a catheter will specifically be inserted by a needling position, a puncture angle, the size of a patient's body, etc. into the left subclavian vein of an opposite hand, for example when performing a right subclavian vein puncture, it is desirable. Compared with a straight catheter or the catheter which has only one bend, since an angle with ***** which collides with a blood vessel wall becomes small and a load when running to a blood vessel wall becomes smaller, the catheter with the stylette of this invention projected from the tip of KANYURA is preferred.

[0023] As mentioned above, although the stylette 2 has the shape which curved to angle theta₁ in the 1st bend 31 in the tip part 300 of the stylette, The tip 34 of the stylette may be located in the tip 33 side of a catheter rather than the 2nd bend 32, and may have the shape which curved by angle theta₂ in the 2nd bend 32 like the above-mentioned catheter 1. When the catheter 1 and the stylette 2 both have the 1st bend 31 and 2nd bend 32, When the shape of the tip part 3 of a catheter becomes is easy to be held and the tip 34 of the stylette is located between the 1st bend 31 of the catheter 1, and the 2nd bend 32, the portion by the side of a tip will have pliability rather than the tip part 3 of a catheter, especially the 2nd bend 32.

[0024] The stylette 2 inserted in the lumen of the catheter 1 does not project from the tip 33 of a catheter, i.e., it has the catheter with the stylette of this invention so that the tip 34 of the stylette may not project from the tip 33 of a catheter. If the catheter with the stylette has such a structure, since it has the effect to a blood vessel of being able to weight low by dashing and not damaging a blood vessel wall, at the time of catheter implantation, it is desirable. As an appropriate range of the above-mentioned thrust reliance load, specifically, For example; when the stylette made from stainless steel of 0.025-inch (inch) (a body part and a tip part the same rigidity) is inserted in the single lumen catheter of 16G size most often as an intravenous hyperalimentation therapy used, it is preferred that it is less than 0.5N. Here, the above-mentioned thrust reliance load is an additional load generated by inserting the stylette, as shown in a following formula (1). It dashes and weights. $[N] = (\text{Load } [N] \text{ when the specified length stylette is inserted}) - (\text{Load at the time of stylette un-inserting } [N])$ (1)

[0025] The above-mentioned thrust reliance load uses Shimadzu Corp. make universal testing machine autograph AG-1, From the tip of the straight catheter which inserted the stylette of predetermined length, grasp the place of 5 cm, and push in this catheter, and it is made to move vertically by speed 100 mm/min, it dashes against a flat surface, a catheter bends, and it asks as average value ($n=5$) of the load in a **** time. To the polyurethane catheter (valve-flow-coefficient flex time, TERUMO [CORP.] make: single lumen 30cm) of 16G size. 0. It dashes with the position at the tip of the stylette from the tip of the catheter in the case of the catheter with the stylette which inserts and forms the stylette made from stainless steel of 025-inch (inch) (a spring type and a body part tip part the same rigidity), and the relation of a load is shown in the following table 1.

[0026]
[Table 1]

表1

カテーテルの先端からの スタイルットの先端位置(mm)	0	2	5	10	20	30
突き当り加重(N)	0.90	0.60	0.48	0.33	0.26	0.25

[0027]The result shown in Table 1 shows that the catheter with which the stylette is not inserted dashes, more than 0.5N is high compared with the load, and a blood vessel wall may be stimulated strongly, when the position at the tip 34 of the stylette from the tip 33 of a catheter is smaller than 2 mm. On the other hand by the case where the position at the tip 34 of the stylette from the tip 33 of a catheter is not less than 5 mm. Since the difference of this load becomes less than 0.5N even if the catheter with which the stylette is not inserted dashes and it compares with a load, the stimulus to a blood vessel wall is low, and it turns out that a blood vessel wall is not stimulated more than needed. Therefore, as a position at the tip 34 of the stylette, it is preferred that the tip 34 of the stylette is located from the tip 33 of a catheter after 5 mm.

[0028]In the time of blood vessel insertion that the position at the tip 34 of the stylette is located in the 1-cm or more tip side rather than the 1st bend 31 established in the catheter 1, Since direction of the tip 33 of the catheter which the body part of the catheter was not twisted and was incurvated in the 1st bend 31 can be grasped certainly, since a way person becomes possible [inserting a catheter in comfort, even if it is an unripe person], he is preferred. On the other hand, when the tip 34 of the stylette is located in the body part side rather than the 1st bend 31, the body part 4 of a catheter may be twisted, and cannot grasp direction of the tip 33 of a catheter, but may interfere with the inserting operation of a catheter. The position at the tip 34 of the stylette becomes it is also the same as when located in less than 1 cm by the side of a tip from the 1st bend 31, and more nearly deficient in the capability to hold the shape of the catheter by the side of a tip than the tip 34 of the stylette. As mentioned above, as an optimum position range at the tip 34 of the stylette, it is after 5 mm and it is more preferred than the tip 33 of a catheter to be located in the 1-cm or more tip side rather than the 1st bend 31.

[0029]the blood vessel wall of a catheter -- the tip side may be formed rather than the 1st bend 31 of the catheter 1 and the stylette 2 so that rigidity may become low rather than each body part, so that it may dash and a load may be lowered. Specifically, inclination physical properties may be given so that rigidity may become low from the tip 34 of the stylette before the 1st bend 31 in the structure of the stylette 2. On the other hand, as for the stylette 2, in the range which does not carry out plastic deformation, it is preferred that stability like a spring is shown to modification. Until a catheter begins to project from KANYURA and the 1st bend 31 specifically passes through the tip of KANYURA at the time of catheter implantation, Since the shape of KANYURA is straight, the 1st bend 31 formed in 30 to 70 degrees (θ_1) is corrected so that it may become comparatively straight, but when the 1st bend 31 projects from the tip of KANYURA, the 1st bend 31 is easily restored to angle θ_1 . Since the way person can recognize this phenomenon with the feeling at hand, when the 1st bend 31 is formed in the place of 5 cm from the tip 33 of the catheter, it becomes possible to recognize that the catheter went inside the body 5 cm ahead of the tip of KANYURA, for example. In a case like the conventional catheter, for example, the straight catheter with which it is not equipped with the stylette. Since the position at the tip of a catheter had to be guessed from the physical relationship of the overall length of KANYURA, and the depth mark currently printed by the catheter, hand feeling which was mentioned above becomes possible [giving the information on the position at the tip 33 of a catheter exactly], and is dramatically effective in a way person.

[0030]In the catheter with the stylette of this invention, in order to recognize the directivity at the tip 33 of a catheter visually, it is preferred to attach a mark to the catheter connector 51 or the stylette connector 52, and it is good also considering the above-mentioned depth mark as a mark. Specifically, the bending direction in a bend is good for the stylette connector 52 to print or stamp the mark of the arrow of an opposite direction (the upper part is pointed out in drawing 1), etc., and to make it this mark certainly turn to a top at the time of catheter implantation. By taking such composition, since the tip 33 of a catheter certainly comes to turn to a counter direction with a mark and it can insert in superior vena cava easily, it is desirable.

[0031]Here, as construction material of the catheter mentioned above, what has flexibility is preferred. Since the Polymer Division elastomer is illustrated suitably and it is shown below as such a thing, it is more preferred that it is thermoplastic polyurethane. Thermoplastic polyurethane has biocompatibility and high haemocompatibility, and is comparatively used also for long-term detention. After changing the Polymer Division elastomer to desired shape, in order that it may heat-treat at the temperature more than the glass transition temperature of this Polymer Division elastomer and may demonstrate shape memory nature by cooling ***** with the shape, It is also possible to change shape to a desired form moderately, and since shape can be changed to a desired angle and curvature also about the 1st and 2nd bends of the above, it is desirable. The elastic modulus of such a

Polymer Division elastomer shows temperature dependence, and it softens it, so that an elevated temperature is generally used. Since it also has absorptivity further case [like thermoplastic polyurethane], after being detained in a blood vessel, it softens with both body temperature and blood, and it is eased gradually and the shape which has a bend can also be in a comparatively straight state. Therefore, since the contact in particular to the blood vessel wall by the shape given beforehand does not pose a problem, either, it is desirable. If such a material is used, it is also possible by performing ***** coating antithrombotic grant and to carry out antibacterial grant with a catheter, for example.

[0032]As a material of the stylette inserted in the lumen of a catheter, Metal, such as stainless steels, such as metal, for example, a spring wire, and a stranded wire, a NiTi alloy, and a NiTi alloy with which resin was covered, and/. Or since it becomes possible [giving moderate rigidity also to a very soft catheter] to use the polymer material of rates of high elasticity, such as nylon and polyester, it is desirable.

[0033]The outside surface of the above-mentioned catheter and the stylette on a water soluble polymer and a concrete target. A polyvinyl pyrrolidone, methyl-vinyl-ether maleic anhydride sodium, It covers with polyacrylamide hydrolyzate, sodium alginate, polyvinyl sulfonic acid soda, the ammonium salt of a methyl-vinyl-ether maleic anhydride, a polyacrylamide quaternary compound, etc., and may be made to make lubricity hold by soaking in water or an aqueous solution. For example, by wiping the surface of a catheter lightly with the gauze etc. which were dipped in heparinized saline, humidity of the water soluble polymer can be carried out, and lubricity can be given.

[0034]In the catheter with the stylette of this invention, the stylette inserted in the lumen of a catheter acts as substitution of the conventional guidewire, and it becomes possible to make it introduce easily to an intravascular desired region of it. The tip part of a catheter and the tip part of the stylette double with the blood vessel shape of an introductory target part, Are curving in the almost same position, and the tip of the stylette projects from the tip of a catheter, and from a thing [***]. When inserting the catheter into the blood vessel, there is no possibility of damaging a blood vessel wall by the tip of the stylette, and safety and since a catheter can be made to advance into a right location (for example, superior vena cava) correctly and easily, an unskilled person is also preferred. The stylette connector with which the base end of the stylette is equipped, Since the lumen which can pass fluids, such as drugs, is provided as mentioned above, Since a drug solution can be poured into the lumen of a catheter through the lumen of a stylette connector if this stylette connector is made to fix to a catheter connector, Since it is not necessary to carry out extraction of the stylette from a catheter in the case of the check of priming operation and the catheter blood vessel detention by attracting blood and recognizing the back run visually, it is desirable.

[0035]

[Example]The catheter with the stylette concerning one working example of this invention, A [who consist of thermoplastic polyurethane (polycarbonate system polyurethane, Shore hardness 98A) which is a flexible synthetic resin / outer diameter phi1. 5mm, inside diameter phi1. 0mm, and 300 mm of catheter effective length] tube shape catheter, The catheter connector made of polypropylene resin which adhered to the base end of this catheter, . One end was fixed to the central part of the lumen of this catheter connector, and were provided in it so that the other end might make the lumen of a catheter insert in and might finish 2 cm before [tip] a catheter. It consists of stylette which consists of an outside phi0.6mm spring wire made from stainless steel, and a stylette connector made from polypropylene which adhered to the base end of this stylette. In order to use this catheter with the stylette for an intravenous hyperalimentation therapy, it has two bends so that it may be easy to make it detain in superior vena cava.

The 1st bend is a 5-cm position from the tip of a catheter, and the 2nd bend is in a 2-cm position from the tip of a catheter.

θ_1 , [in / in the angle of the curve in the above-mentioned bend / the 1st bend of the above] is 45 degrees.
 θ_2 in the 2nd bend of the above is 15 degrees.

[0036]

[Effect of the Invention]Since, as for the catheter with the stylette of this invention, direction Hecate Tell of superior vena cava will certainly be inserted in every needling position if the curved shape of the tip part of a catheter and direction are maintained certainly and perform the direction check at the time of insertion. Also in an unripe way person, since [to blood vessels other than superior vena cava] catheter detention operation can be easily performed with sense of security, without carrying out involvement, it is useful.

[Translation done.]

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TECHNICAL FIELD

[Field of the Invention]This invention relates to the catheter which is inserted from a body surface and detained in the inside of the body. It is inserted in the inside of the body especially by a subclavian puncture method, and the tip of a catheter is related with the catheter with the stylette used for the intravenous hyperalimentation therapy detained in superior vena cava.

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PRIOR ART

[Description of the Prior Art]Conventionally, when performing an intravenous hyperalimentation therapy, a central venous catheter is generally detained in superior vena cava.Although the schematic diagram of the blood vessel near superior vena cava (venae centrales hepatis) when the patient has turned to the transverse plane is specifically shown in drawing 7, At such a catheter leaving method, after it carries out the puncture of division type KANYURA which generally has an inner needle by a subclavian vein puncture method and a needle tip reaches a blood vessel, extraction of the inner needle is carried out and the tip of a catheter is detained in the optimum detention region shown in superior vena cava with the slash via above-mentioned KANYURA. When a way person performs blood vessel reservation, in the approach from an internal jugular vein, hardly become a problem, but. In the case of a subclavian vein puncture, there was a problem that there was a risk of carrying out involvement (the poor position of a catheter: mislodging) to the subclavian vein of an opposite hand, etc. depending on the blood vessel arrival position of a needle tip especially with an internal jugular vein, the vena jugularis externa, or a needling position. Here, the blood vessel arrival position of the needle tip which may carry out involvement is carried out [that it is near / like the turning point of a subclavian vein and an internal jugular vein / a tee in many cases, and]. For example, in order to make a site of puncture exaggerate, a patient is made to turn to the left, when a way person does a puncture towards the right subclavian vein as shown in drawing 8, but the right internal jugular vein becomes the arrangement which becomes linear shape from the right subclavian vein at this time. In in such a case, the stage where a catheter projects in the case where a straight catheter is inserted, from the tip (side which carried out the puncture to the blood vessel) of division KANYURA if a needle tip reaches near the tee shown by the arrow rather than the optimum puncture region. Before riding the flow of blood and going downward (the direction of superior vena cava), it has become that it is easy to be inserted toward the direction of the right internal jugular vein. Once the tip of blood vessel Hecate Tell thinner than superior vena cava other than superior vena cava carries out involvement, The tip of the catheter became that it is easy to hit a blood vessel wall, or vascular endothelium was stimulated, and there was a problem that the extravasation (Extravasation of Fluids) that the infusion of nutrient of the hypertonicity supplied from a catheter encroaches on the outside of the blood vessel occurred.

[0003]Some trials are made in order to solve the problem of the involvement to blood vessels other than the above-mentioned superior vena cava. For example, by the method of a description, to JP,H8-224312,A. The catheter which inserted the stylette which consists of stranded wires is indicated, this stylette is the structure bent from the tip of the stylette to about ten to 15 bend angles in an about 12-mm position, and the tip of the stylette is located in the nearly tip of a catheter. Although it is indicated by considering it as the shape mentioned above in the gazette that detention to superior vena cava is certainly possible, In near the tee from the subclavian vein which has comparatively big space in such a catheter since the bend is a nearly tip of a catheter as shown in drawing 9 to superior vena cava, Since this catheter rotated in every direction in the stage where a catheter projects from the tip of KANYURA 10 as shown in drawing 10, it was not effective for making it located in an optimum direction. From this, in order to turn the tip of a catheter to the superior-vena-cava side, at the time of insertion, it always needed to take care. therefore — a way person requires [that the big sense of security about not carrying out involvement of the catheter cannot be obtained, and] skill too — experience — the involvement of the catheter may have been started in the unripe resident. Since the stylette is inserted to the nearly tip of a catheter, when pushing intensity is too strong and the tip of a catheter projects from division KANYURA, for example. Like the case where the tip of the stylette has projected from the tip of the catheter, the tip of the catheter contacted the blood vessel wall and there were problems, like there is a possibility of damaging a blood vessel wall.

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EFFECT OF THE INVENTION

[Effect of the Invention] Since, as for the catheter with the stylette of this invention, direction Hecate Tell of superior vena cava will certainly be inserted in every needling position if the curved shape of the tip part of a catheter and direction are maintained certainly and perform the direction check at the time of insertion. Also in an unripe way person, since [to blood vessels other than superior vena cava] catheter detention operation can be easily performed with sense of security, without carrying out involvement, it is useful.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention]An object of this invention is to provide the catheter with the stylette which can insert without guidance by a guidewire correctly, without carrying out involvement especially to a branching blood vessel and the superior vena cava in an intravenous hyperalimentation therapy, and does not damage a blood vessel.

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MEANS

[Means for Solving the Problem] This invention persons by using a catheter with the stylette which has a specific structure where stylette and a catheter curve by the same part as a result of inquiring wholeheartedly that SUBJECT mentioned above should be solved. It found out safety and that a catheter could be carried forward to a desired position correctly and easily, and resulted in this invention. That is, this invention provides following the (1) – (7) with a catheter with the stylette of a description.

[0006](1) A flexible catheter which consists of a tip part, a body part, and a base end, and stylette which consists of a tip part, a body part, and a base end which were inserted in a lumen of this catheter. Are the catheter with the stylette currently engaged and in a base end of this catheter, and a base end of this stylette a tip part of the above-mentioned catheter, and a tip part of the above-mentioned stylette. A catheter with the stylette curving in the almost same position and not having projected a tip of the above-mentioned stylette from a tip of the above-mentioned catheter according to blood vessel shape of an introductory target part.

[0007](2) A catheter with the stylette given in the above (1) provided with the 1st bend that the above-mentioned catheter is a 4–8-cm position from a tip, and is curving in the almost same position as the above-mentioned stylette, and the 2nd bend that is curving in a position by the side of a tip rather than this 1st bend.

[0008](3) A catheter with the stylette given in the above (2) in which angle theta₁ of a line by which the 1st bend of the above passes along a body part of the above-mentioned catheter, and a line which passes along the 1st portion of a tip part of the above-mentioned catheter that is a straight line mostly to make is formed so that it may become 30 to 70 degrees.

[0009](4) The above (2) in which the 2nd bend of the above is curving in a 1–3-cm position from a tip of the above-mentioned catheter, or a catheter with the stylette given in (3).

[0010](5) The 2nd bend of the above, the above -- a catheter -- a tip part -- almost -- a straight line -- it is -- the -- one -- a portion -- passing -- a line -- the above -- a catheter -- a tip part -- almost -- a straight line -- it is -- the -- two -- a portion -- passing -- a line -- making -- an angle -- theta -- two -- five -- 45 -- a degree -- becoming -- as -- forming -- having -- **** -- the above -- (two --) -- (four --) -- either -- a description -- the stylette -- with -- a catheter .

[0011](6) A catheter with the stylette given in either of above-mentioned (2) – (5) currently formed rather than the 1st bend of the above-mentioned catheter so that, as for the tip side, rigidity may become low rather than a body part of the above-mentioned catheter.

[0012](7) A catheter with the stylette given in either of above-mentioned (1) – (6) whose above-mentioned catheters are catheterization of vein for intravenous hyperalimentation with which a tip part is detained in superior vena cava.

[0013]

[Embodiment of the Invention] The flexible catheter with which the catheter with the stylette of this invention consists of a tip part, a body part, and a base end. The stylette which consists of the tip part, body part, and base end which were inserted in the lumen of this catheter. It is the catheter with the stylette currently engaged in the base end of this catheter, and the base end of this stylette. The tip part of the above-mentioned catheter and the tip part of the above-mentioned stylette double with the blood vessel shape of an introductory target part. It is curved or crooked in the almost same position (only henceforth a "curve"), and the tip of the above-mentioned stylette is a catheter with the stylette not having projected from the tip of the above-mentioned catheter. Although Drawings are used for below and one suitable example is explained to it in detail about the catheter with the stylette of this invention, the catheter with the stylette of this invention is not limited to this.

[0014] As shown in the whole catheter side view with the stylette of this invention of drawing 1, the catheter 1 comprises the tip part 3, the body part 4, and the base end 5, and is, and the stylette 2 comprises the tip part 300, the body part 400, and the base end 500. As it is indicated in the enlarged drawing of the tip part of drawing

2 and the catheter with the stylette of this invention of drawing 3 as a tip part, here, It is the portion into which the tip side is curving from the 1st bend 31 including the 1st bend 31 where the catheter 1 and the stylette 2 are curving in the almost same position, and a body part is a portion into which the catheter 1 and the stylette 2 are not curving.

[0015]A base end is the portion and this add-on with which add-on (the catheter connector 51, the stylette connector 52, and the lock part 53) sticks to the catheter 1 and the stylette 2, as shown in the enlarged drawing of the base end of the catheter with the stylette of this invention of drawing 4. Specifically, the above-mentioned base end is equipped with the catheter connector 51 which can fix the catheter 1, and the stylette connector 52 which this catheter connector 51 and fitting are possible, and can fix further the stylette 2 inserted in the lumen of the catheter connector 51. It is the above-mentioned stylette connector's 52 having the lock part 53, having a locking mechanism of this lock part 53, and carrying out lock fitting of the catheter connector 51 and the stylette connector 52, Wearing immobilization of the stylette connector 52 is carried out certainly at the catheter connector 51. Therefore, the catheter connector 51 into which male lure can fit with the above-mentioned base end, the stylette connector 52 and the lock part 53, the portion that touches this catheter connector 51 of the catheter 1 further, And it is the thing of a portion which inserts in the lumen of this catheter connector 51 of the stylette 2, and touches the stylette connector 52.

[0016]By providing the lumen which opened from the tip of the stylette connector 52 to the back end for free passage, and connecting a syringe etc. to this back end, the above-mentioned stylette connector 52 is made composition so that passage of a fluid (drug solution) may be attained. It becomes possible to carry out that check which the tip 33 of priming by the physiological saline in a catheter, etc. and the catheter by viewing the back run of blood is contained in the blood vessel, without this extracting the stylette 2 from the catheter 1, or is not contained.

[0017]the 1st bend 31 in the above-mentioned tip part -- the tip part 3 of a catheter, the body part 4 of a catheter and the tip part 300 of the stylette and the body part 400 of the stylette, and ***** -- it being the bend which is curving in the same position, and, It is more preferred than the tip 33 of a catheter to be formed in the range of 4-8 cm, and it is more preferred to be formed in the range which is 4.5-6 cm. The angle of the line by which the 1st bend 31 of the above passes along the body part 4 of a catheter, and the line which passes along the 1st portion of the tip part 3 of a catheter that is a straight line mostly to make, And so that it may be shown in the angle of the line which passes along the body part 400 of the stylette, and the line which passes along the 1st portion of the tip part 3 of the stylette that is a straight line mostly to make, i.e., drawing 3. If the angle of the dashed line which extended the body part 4 of a catheter and the body part 400 of the stylette, and the dashed line which extended the virtual straight line to which it is not curving from the 1st bend 31 to the 2nd bend 32 to make is made into angle theta₁, It is preferred to be formed so that angle theta₁ may become a range which is 30 to 70 degrees, and it is 40 to 50 degrees still more preferably 35 to 60 degrees more preferably. In the definition of the angle which the account of the upper makes, although the tip part shown in drawing 3 is explained as a structure bent linearly in the 1st bend 31 and 2nd bend 32, the catheter of this invention has structure which curved in the bend like the tip part shown in drawing 2. When it hits a blood vessel wall, it is desirable from the Reason which cannot damage a blood vessel wall easily.

[0018]By making the formation position of the 1st bend 31 of the above, and angle theta₁ form in a mentioned range, When carrying out the puncture of the catheter near the turning point of a subclavian vein and an internal jugular vein constituting the cause of involvement mentioned above, as shown in drawing 5 and 6, since near the tip part of the catheter projected from KANYURA 10 serves as shape which does not go to any blood vessels other than an optimum detention region, it is preferred. Therefore, by making the 1st bend 31 form in the tip part 3 of a catheter, and the tip part 300 of the stylette, Rather than near the tee of a subclavian vein and an internal jugular vein, of course, when the puncture has been carried out near a tee, it becomes possible from the distance by the side of a shoulder to insert direction Hecate Tell of superior vena cava certainly.

[0019]If the formation position of the 1st bend 31 of the above is formed in addition to the mentioned range, a possibility that the tip 33 of a catheter will carry out involvement to the subclavian vein of an opposite hand will arise. When the above-mentioned angle theta₁ is less than 30 degrees, There is a danger that an angle will be too small and the tip 33 of a catheter will be inserted in an internal jugular vein, and when it is more than 70 degrees, When the tip 33 of a catheter is inserted in superior vena cava, the tip 33 of a catheter hits a blood vessel wall easily, and a blood vessel wall may be damaged at the time of catheter implantation.

[0020]Bend-radii rho₁ in the 1st bend 31 of the catheter with the stylette of this investigation, As for bend-radii rho₁ in a bend, since there is a possibility that a bend may become sharp and may stimulate a blood vessel, and the case below 3 mm may not understand anymore well the hand feeling at the time of the catheter implantation

which was curving too much and was mentioned above when it is more than 50 mm, it is preferred that it is the range of 3~50 mm.

[0021]As for the above-mentioned catheter 1, in the tip part, the 2nd bend 32 is established in the position by the side of the tip 33 of a catheter from the 1st bend 31 of the above. That is, the catheter with the stylette of this invention has the shape which curved in the 1st bend 31 and 2nd bend 32 in the tip part 3 of a catheter. Here, as for the 2nd bend 32 of the above, it is more preferred than the tip 33 of a catheter to be formed in the range of 1~3 cm, and it is more preferred to be formed in the range which is 1.5 to 2.5 cm. the angle of the line by which the 2nd bend 32 of the above passes along the 1st portion of the tip part 3 of a catheter it is [portion] a straight line mostly, and the line which passes along the 2nd portion of the tip part 3 of a catheter that is a straight line mostly to make, i.e., drawing 3, -- ** -- like, If the angle of the dashed line which extended the virtual straight line to which it is not curving from the 1st bend 31 to the 2nd bend 32, and the dashed line which extended the virtual straight line to which it is not curving from the 2nd bend 32 to the tip 33 of a catheter to make is made into angle theta₂, It is preferred that angle theta₂ is a range which is 5 to 45 degrees, and it is 10 to 30 degrees still more preferably 7 to 40 degrees more preferably. As mentioned above, in the definition of the angle which the account of the upper makes, the tip part shown in drawing 3 is explained as a structure bent linearly in the 1st bend 31 and 2nd bend 32, but the catheter of this invention has structure which curved in the bend like the tip part shown in drawing 2. When it hits a blood vessel wall, it is desirable from the Reason which cannot damage a blood vessel wall easily.

[0022]By making the formation position of the 2nd bend 32 of the above, and angle theta₂ form in a mentioned range, since the detention operation to superior vena cava becomes more certain, it is desirable. Since it may stop saying that the 1st bend 31 is the stage projected from KANYURA, and the tip 33 of a catheter will specifically be inserted by a needling position, a puncture angle, the size of a patient's body, etc. into the left subclavian vein of an opposite hand, for example when performing a right subclavian vein puncture, it is desirable. Compared with a straight catheter or the catheter which has only one bend, since an angle with ***** which collides with a blood vessel wall becomes small and a load when running to a blood vessel wall becomes smaller, the catheter with the stylette of this invention projected from the tip of KANYURA is preferred.

[0023]As mentioned above, although the stylette 2 has the shape which curved to angle theta₁ in the 1st bend 31 in the tip part 300 of the stylette, The tip 34 of the stylette may be located in the tip 33 side of a catheter rather than the 2nd bend 32, and may have the shape which curved by angle theta₂ in the 2nd bend 32 like the above-mentioned catheter 1. When the catheter 1 and the stylette 2 both have the 1st bend 31 and 2nd bend 32, When the shape of the tip part 3 of a catheter becomes is easy to be held and the tip 34 of the stylette is located between the 1st bend 31 of the catheter 1, and the 2nd bend 32, the portion by the side of a tip will have pliability rather than the tip part 3 of a catheter, especially the 2nd bend 32.

[0024]The stylette 2 inserted in the lumen of the catheter 1 does not project from the tip 33 of a catheter, i.e., it has the catheter with the stylette of this invention so that the tip 34 of the stylette may not project from the tip 33 of a catheter. If the catheter with the stylette has such a structure, since it has the effect to a blood vessel of being able to weight low by dashing and not damaging a blood vessel wall, at the time of catheter implantation, it is desirable. As an appropriate range of the above-mentioned thrust reliance load, specifically, For example, when the stylette made from stainless steel of 0.025-inch (inch) (a body part and a tip part the same rigidity) is inserted in the single lumen catheter of 16G size most often as an intravenous hyperalimentation therapy used, it is preferred that it is less than 0.5N. Here, the above-mentioned thrust reliance load is an additional load generated by inserting the stylette, as shown in a following formula (1). It dashes and weights. [N]=(Load [N] when the specified length stylette is inserted) - (Load at the time of stylette un-inserting [N]) (1)

[0025]The above-mentioned thrust reliance load uses Shimadzu Corp. make universal testing machine autograph AG-1, From the tip of the straight catheter which inserted the stylette of predetermined length, grasp the place of 5 cm, and push in this catheter, and it is made to move vertically by speed 100 mm/min, it dashes against a flat surface, a catheter bends, and it asks as average value (n= 5) of the load in a **** time. To the polyurethane catheter (valve-flow-coefficient flex time, TERUMO [CORP.] make: single lumen 30cm) of 16G size. 0. It dashes with the position at the tip of the stylette from the tip of the catheter in the case of the catheter with the stylette which inserts and forms the stylette made from stainless steel of 025-inch (inch) (a spring type and a body part tip part the same rigidity), and the relation of a load is shown in the following table 1.

[0026]

[Table 1]

表1

カテーテルの先端からの スタイルットの先端位置(mm)	0	2	5	10	20	30
突き当り加重(N)	0.90	0.60	0.48	0.33	0.26	0.25

[0027]The result shown in Table 1 shows that the catheter with which the stylette is not inserted dashes, more than 0.5N is high compared with the load, and a blood vessel wall may be stimulated strongly, when the position at the tip 34 of the stylette from the tip 33 of a catheter is smaller than 2 mm. On the other hand by the case where the position at the tip 34 of the stylette from the tip 33 of a catheter is not less than 5 mm. Since the difference of this load becomes less than 0.5N even if the catheter with which the stylette is not inserted dashes and it compares with a load, the stimulus to a blood vessel wall is low, and it turns out that a blood vessel wall is not stimulated more than needed. Therefore, as a position at the tip 34 of the stylette, it is preferred that the tip 34 of the stylette is located from the tip 33 of a catheter after 5 mm.

[0028]In the time of blood vessel insertion that the position at the tip 34 of the stylette is located in the 1-cm or more tip side rather than the 1st bend 31 established in the catheter 1, Since direction of the tip 33 of the catheter which the body part of the catheter was not twisted and was incurvated in the 1st bend 31 can be grasped certainly, since a way person becomes possible [inserting a catheter in comfort, even if it is an unripe person], he is preferred. On the other hand, when the tip 34 of the stylette is located in the body part side rather than the 1st bend 31, the body part 4 of a catheter may be twisted, and cannot grasp direction of the tip 33 of a catheter, but may interfere with the inserting operation of a catheter. The position at the tip 34 of the stylette becomes it is also the same as when located in less than 1 cm by the side of a tip from the 1st bend 31, and more nearly deficient in the capability to hold the shape of the catheter by the side of a tip than the tip 34 of the stylette. As mentioned above, as an optimum position range at the tip 34 of the stylette, it is after 5 mm and it is more preferred than the tip 33 of a catheter to be located in the 1-cm or more tip side rather than the 1st bend 31.

[0029]the blood vessel wall of a catheter -- the tip side may be formed rather than the 1st bend 31 of the catheter 1 and the stylette 2 so that rigidity may become low rather than each body part, so that it may dash and a load may be lowered. Specifically, inclination physical properties may be given so that rigidity may become low from the tip 34 of the stylette before the 1st bend 31 in the structure of the stylette 2. On the other hand, as for the stylette 2, in the range which does not carry out plastic deformation, it is preferred that stability like a spring is shown to modification. Until a catheter begins to project from KANYURA and the 1st bend 31 specifically passes through the tip of KANYURA at the time of catheter implantation, Since the shape of KANYURA is straight, the 1st bend 31 formed in 30 to 70 degrees (θ_1) is corrected so that it may become comparatively straight, but when the 1st bend 31 projects from the tip of KANYURA, the 1st bend 31 is easily restored to angle θ_1 . Since the way person can recognize this phenomenon with the feeling at hand, when the 1st bend 31 is formed in the place of 5 cm from the tip 33 of the catheter, it becomes possible to recognize that the catheter went inside the body 5 cm ahead of the tip of KANYURA, for example. In a case like the conventional catheter, for example, the straight catheter with which it is not equipped with the stylette. Since the position at the tip of a catheter had to be guessed from the physical relationship of the overall length of KANYURA, and the depth mark currently printed by the catheter, hand feeling which was mentioned above becomes possible [giving the information on the position at the tip 33 of a catheter exactly], and is dramatically effective in a way person.

[0030]In the catheter with the stylette of this invention, in order to recognize the directivity at the tip 33 of a catheter visually, it is preferred to attach a mark to the catheter connector 51 or the stylette connector 52, and it is good also considering the above-mentioned depth mark as a mark. Specifically, the bending direction in a bend is good for the stylette connector 52 to print or stamp the mark of the arrow of an opposite direction (the upper part is pointed out in drawing 1), etc., and to make it this mark certainly turn to a top at the time of catheter implantation. By taking such composition, since the tip 33 of a catheter certainly comes to turn to a counter direction with a mark and it can insert in superior vena cava easily, it is desirable.

[0031]Here, as construction material of the catheter mentioned above, what has flexibility is preferred. Since the Polymer Division elastomer is illustrated suitably and it is shown below as such a thing, it is more preferred that it is thermoplastic polyurethane. Thermoplastic polyurethane has biocompatibility and high haemocompatibility, and is comparatively used also for long-term detention. After changing the Polymer Division elastomer to desired shape, in order that it may heat-treat at the temperature more than the glass transition temperature of this Polymer Division elastomer and may demonstrate shape memory nature by cooling ***** with the shape, It is also possible to change shape to a desired form moderately, and since shape can be changed to a desired angle and curvature also about the 1st and 2nd bends of the above, it is desirable. The elastic modulus of such a

Polymer Division elastomer shows temperature dependence, and it softens it, so that an elevated temperature is generally used. Since it also has absorptivity further case [like thermoplastic polyurethane], after being detained in a blood vessel, it softens with both body temperature and blood, and it is eased gradually and the shape which has a bend can also be in a comparatively straight state. Therefore, since the contact in particular to the blood vessel wall by the shape given beforehand does not pose a problem, either, it is desirable. If such a material is used, it is also possible by performing ***** coating antithrombotic grant and to carry out antibacterial grant with a catheter, for example.

[0032]As a material of the stylette inserted in the lumen of a catheter, Metal, such as stainless steels, such as metal, for example, a spring wire, and a stranded wire, a NiTi alloy, and a NiTi alloy with which resin was covered, and/. Or since it becomes possible [giving moderate rigidity also to a very soft catheter] to use the polymer material of rates of high elasticity, such as nylon and polyester, it is desirable.

[0033]The outside surface of the above-mentioned catheter and the stylette on a water soluble polymer and a concrete target. A polyvinyl pyrrolidone, methyl-vinyl-ether maleic anhydride sodium, It covers with polyacrylamide hydrolyzate, sodium alginate, polyvinyl sulfonic acid soda, the ammonium salt of a methyl-vinyl-ether maleic anhydride, a polyacrylamide quaternary compound, etc., and may be made to make lubricity hold by soaking in water or an aqueous solution. For example, by wiping the surface of a catheter lightly with the gauze etc. which were dipped in heparinized saline, humidity of the water soluble polymer can be carried out, and lubricity can be given.

[0034]In the catheter with the stylette of this invention, the stylette inserted in the lumen of a catheter acts as substitution of the conventional guidewire, and it becomes possible to make it introduce easily to an intravascular desired region of it. The tip part of a catheter and the tip part of the stylette double with the blood vessel shape of an introductory target part, Are curving in the almost same position, and the tip of the stylette projects from the tip of a catheter, and from a thing [***]. When inserting the catheter into the blood vessel, there is no possibility of damaging a blood vessel wall by the tip of the stylette, and safety and since a catheter can be made to advance into a right location (for example, superior vena cava) correctly and easily, an unskilled person is also preferred. The stylette connector with which the base end of the stylette is equipped, Since the lumen which can pass fluids, such as drugs, is provided as mentioned above, Since a drug solution can be poured into the lumen of a catheter through the lumen of a stylette connector if this stylette connector is made to fix to a catheter connector, Since it is not necessary to carry out extraction of the stylette from a catheter in the case of the check of priming operation and the catheter blood vessel detention by attracting blood and recognizing the back run visually, it is desirable.

[Translation done.]

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EXAMPLE

[Example]The catheter with the stylette concerning one working example of this invention, A [who consist of thermoplastic polyurethane (polycarbonate system polyurethane, Shore hardness 98A) which is a flexible synthetic resin / outer diameter phi1. 5mm, inside diameter phi1. 0mm, and 300 mm of catheter effective length] tube shape catheter, The catheter connector made of polypropylene resin which adhered to the base end of this catheter, . One end was fixed to the central part of the lumen of this catheter connector, and were provided in it so that the other end might make the lumen of a catheter insert in and might finish 2 cm before [tip] a catheter. It consists of stylette which consists of an outside phi0.6mm spring wire made from stainless steel, and a stylette connector made from polypropylene which adhered to the base end of this stylette. In order to use this catheter with the stylette for an intravenous hyperalimentation therapy, it has two bends so that it may be easy to make it detain in superior vena cava.

The 1st bend is a 5-cm position from the tip of a catheter, and the 2nd bend is in a 2-cm position from the tip of a catheter.

θ_1 [in / in the angle of the curve in the above-mentioned bend / the 1st bend of the above] is 45 degrees.
 θ_2 in the 2nd bend of the above is 15 degrees.

[Translation done.]

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1]It is the whole catheter side view with the stylette of this invention.

[Drawing 2]It is an enlarged drawing of the tip part of the catheter with the stylette of this invention.

[Drawing 3]It is an enlarged drawing of the tip part of the catheter with the stylette of this invention.

[Drawing 4]It is an enlarged drawing of the base end of the catheter with the stylette of this invention.

[Drawing 5]It is a schematic diagram when the 1st bend of the catheter with the stylette of this invention has projected from KANYURA.

[Drawing 6]It is a schematic diagram when the catheter with the stylette of this invention is further inserted in the back from the state which shows in drawing 5.

[Drawing 7]It is a schematic diagram of the blood vessel near superior vena cava (venae centrales hepatis) when the patient has turned to the transverse plane.

[Drawing 8]It is a schematic diagram of the blood vessel near superior vena cava (venae centrales hepatis) when the patient has turned to the left.

[Drawing 9]It is the general drawing of the conventional catheter with the stylette.

[Drawing 10]It is a schematic diagram when the conventional catheter with the stylette has projected from KANYURA.

[Description of Notations]

1 Catheter

2 Stylette

3 The tip part of a catheter

4 The body part of a catheter

5 The base end of a catheter

10 KANYURA

31 The 1st bend

32 The 2nd bend

33 The tip of a catheter

34 The tip of the stylette

51 Catheter connector

52 Stylette connector

53 Lock part

300 The tip part of the stylette

400 The body part of the stylette

500 The base end of the stylette

[Translation done.]

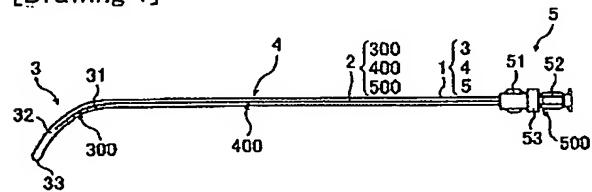
* NOTICES *

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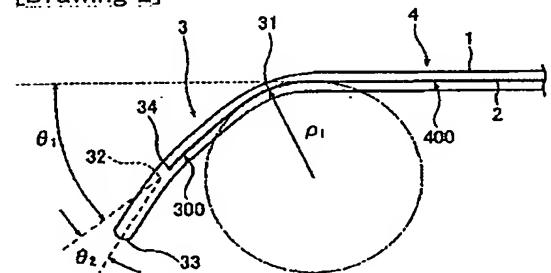
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DRAWINGS

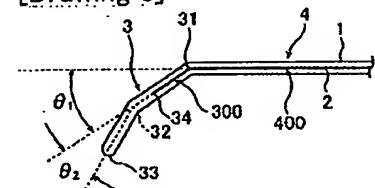
[Drawing 1]



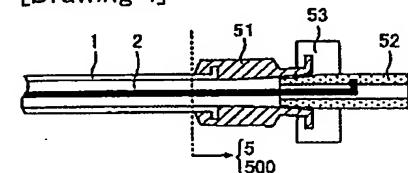
[Drawing 2]



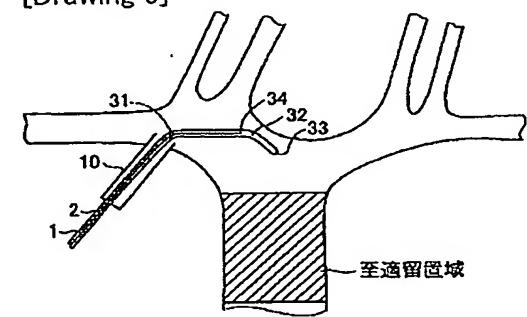
[Drawing 3]



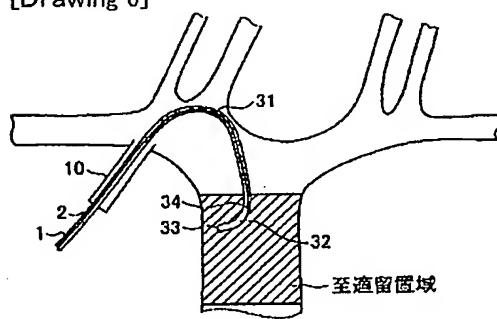
[Drawing 4]



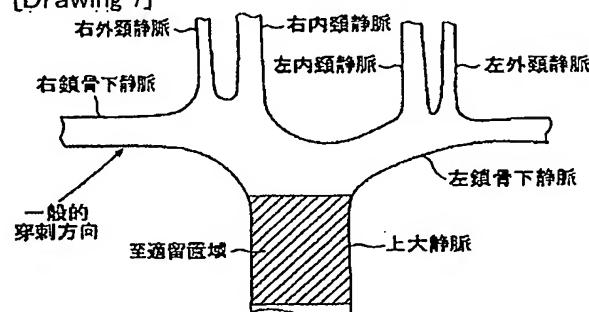
[Drawing 5]



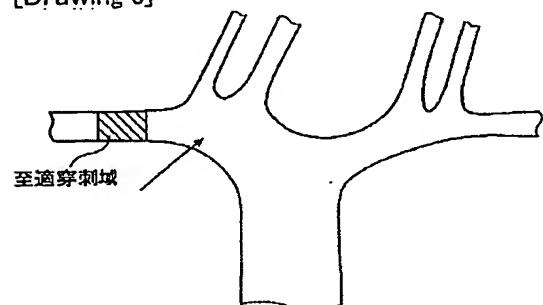
[Drawing 6]



[Drawing 7]



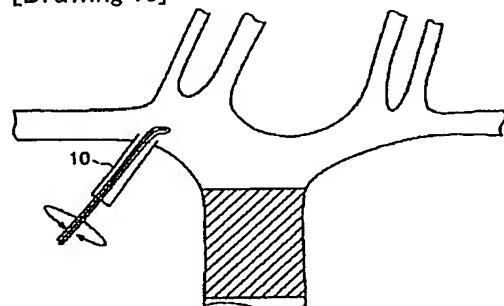
[Drawing 8]



[Drawing 9]



[Drawing 10]



[Translation done.]

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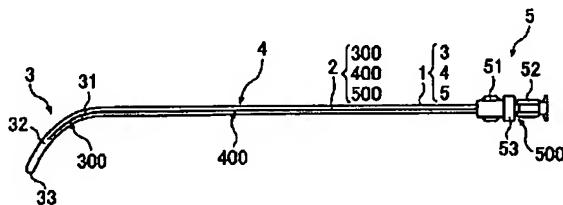
BB14 CC08 DD10 HH08

(54)【発明の名称】 スタイレット付きカテーテル

(57)【要約】

【課題】ガイドワイヤによる案内なしに、分岐血管、特に、高カロリー輸液療法における上大静脈に対して、迷入させることなく正確に挿入することができ、かつ血管を損傷することのないスタイレット付きカテーテルの提供。

【解決手段】先端部と本体部と基端部とからなる可撓性のカテーテルと、該カテーテルの内腔に挿通された先端部と本体部と基端部とからなるスタイレットとが、該カテーテルの基端部と該スタイレットの基端部とで係合されているスタイレット付きカテーテルであって、前記カテーテルの先端部および前記スタイレットの先端部は、導入目的部位の血管形状に合わせて、ほぼ同じ位置で湾曲しており、前記スタイレットの先端は、前記カテーテルの先端から突出していないことを特徴とするスタイレット付きカテーテル。



【特許請求の範囲】

【請求項1】先端部と本体部と基端部とからなる可撓性のカテーテルと、該カテーテルの内腔に挿通された先端部と本体部と基端部とからなるスタイルットとが、該カテーテルの基端部と該スタイルットの基端部とで係合されているスタイルット付きカテーテルであって、前記カテーテルの先端部および前記スタイルットの先端部は、導入目的部位の血管形状に合わせて、ほぼ同じ位置で湾曲しており、前記スタイルットの先端は、前記カテーテルの先端から突出していないことを特徴とするスタイルット付きカテーテル。

【請求項2】前記カテーテルは、先端から4~8cmの位置であり、かつ前記スタイルットとほぼ同じ位置で湾曲している第1の湾曲部と、該第1の湾曲部よりも先端側の位置で湾曲している第2の湾曲部とを備える請求項1に記載のスタイルット付きカテーテル。

【請求項3】前記第1の湾曲部は、前記カテーテルの本体部を通る線と前記カテーテルの先端部のほぼ直線である第1の部分を通る線とのなす角θ₁が30~70度になるように形成されている請求項2に記載のスタイルット付きカテーテル。

【請求項4】前記第2の湾曲部は、前記カテーテルの先端から1~3cmの位置で湾曲している請求項2または3に記載のスタイルット付きカテーテル。

【請求項5】前記第2の湾曲部は、前記カテーテルの先端部のほぼ直線である第1の部分を通る線と前記カテーテルの先端部のほぼ直線である第2の部分を通る線とのなす角θ₂が5~45度になるように形成されている請求項2~4のいずれかに記載のスタイルット付きカテーテル。

【請求項6】前記カテーテルの第1の湾曲部よりも先端側は、前記カテーテルの本体部よりも剛性が低くなるように形成されている請求項2~5のいずれかに記載のスタイルット付きカテーテル。

【請求項7】前記カテーテルは、先端部が上大静脈に留置される高カロリー輸液用静脉カテーテルである請求項1~6のいずれかに記載のスタイルット付きカテーテル。

【発明の詳細な説明】

【0001】

【発明の属する技術分野】本発明は、体表面より挿入し体内に留置するカテーテルに関する。特に鎖骨下穿刺法により体内に挿入され、カテーテルの先端が上大静脈へ留置される高カロリー輸液療法に用いられるスタイルット付きカテーテルに関する。

【0002】

【従来の技術】従来より、高カロリー輸液療法を行う場合、一般的に、上大静脈に中心静脉カテーテルが留置さ

れる。具体的には、図7に患者が正面を向いている時の上大静脈（中心静脈）付近の血管の概略図を示すが、このようなカテーテル留置法では、一般的には内針を有する分割式カニューラを鎖骨下静脈穿刺法により穿刺し、針先が血管に到達した後、内針を抜去し、上記カニューラを介して上大静脈に斜線で示された至適留置域にカテーテルの先端が留置される。術者が血管確保を行う際、内頸静脈からのアプローチでは殆ど問題とはならないが、特に鎖骨下静脈穿刺の場合、針先の血管到達位置によっては内頸静脈、外頸静脈、あるいは穿刺位置とは反対側の鎖骨下静脈等に迷入（カテーテルの位置不良：mislodging）する危険があるという問題があった。ここで、迷入する可能性のある針先の血管到達位置は、鎖骨下静脈と内頸静脈の分岐点のような分岐部付近であることが多いとされている。例えば、図8に示されるように、術者が右鎖骨下静脈に向けて穿刺する場合、穿刺部位を誇張するために患者は左方向を向くようになると、この時、右内頸静脈は右鎖骨下静脈より直線状になるような配置になる。この様な場合、至適穿刺域よりも矢印で示された分岐部付近に針先が到達してしまうと、真っ直ぐなカテーテルを挿入する場合では分割カニューラの先端（血管に穿刺した側）よりカテーテルが突出する段階で、血液の流れに乗って下方向（上大静脈方向）へ行く前に、右内頸静脈の方向に向かって挿入されてしまい易くなっている。一旦、上大静脈以外の上大静脈より細い血管へカテーテルの先端が迷入してしまうと、カテーテルの先端が血管壁に当たり易くなったり、血管内皮を刺激し、カテーテルより供給される高張の栄養輸液が血管外に侵出するといった血管外漏出（Extravasation of Fluids）が発生するという問題があった。

【0003】上記上大静脈以外の血管への迷入といった問題を解決するために、幾つかの試みがなされている。例えば、特開平8-224312号公報に記載の方法では、捺り線からなるスタイルットを挿入したカテーテルが記載されており、該スタイルットは、スタイルットの先端から12mm程度の位置で、曲げ角度10~15度程度に折り曲げた構造であり、スタイルットの先端はカテーテルの先端近傍にある。また、同公報には、上述した形状とすることで確実に上大静脈への留置が可能であると記載されているが、この様なカテーテルでは、図9に示すように湾曲部がカテーテルの先端近傍であるので、比較的大きな空間を有する鎖骨下静脈から上大静脈への分岐部付近においては、図10に示すように、カニューラ10の先端よりカテーテルが突出する段階で該カテーテルがどの方向にも回転できるため最適方向に位置させるには効果的ではなかった。このことから、カテーテルの先端を上大静脈側へ向けるようにするために、挿入時において、常に気をつける必要があった。そのため、術者はカテーテルを迷入させないことについて大き

な安心感を得られないばかりか、やはり熟練を要し、経験未熟な研修医等ではカテーテルの迷入を起こしてしまう可能性があった。また、カテーテルの先端近傍までスタイルットが挿入されているため、例えば、押し込み強度が強すぎ、分割カニューラからカテーテルの先端が突出した際などは、スタイルットの先端がカテーテルの先端より突出している場合と同様、カテーテルの先端が血管壁と接触し、血管壁を傷つけてしまう可能性があるなどの問題点があった。

【0004】

【発明が解決しようとする課題】本発明は、ガイドワイヤによる案内なしに、分岐血管、特に、高カロリー輸液療法における上大静脈に対して、迷入させることなく正確に挿入することができ、かつ血管を損傷することのないスタイルット付きカテーテルを提供することを目的とする。

【0005】

【課題を解決するための手段】本発明者らは、上述した課題を解決すべく銳意研究を行った結果、スタイルットおよびカテーテルが同じ部位で湾曲する特定の構造を有するスタイルット付きカテーテルを使用することにより、安全、正確かつ容易に所望の位置までカテーテルを進めることができることを見出し、本発明に至った。すなわち、本発明は、下記(1)～(7)に記載のスタイルット付きカテーテルを提供する。

【0006】(1) 先端部と本体部と基端部とからなる可撓性のカテーテルと、該カテーテルの内腔に挿通された先端部と本体部と基端部とからなるスタイルットとが、該カテーテルの基端部と該スタイルットの基端部とで係合されているスタイルット付きカテーテルであって、上記カテーテルの先端部および上記スタイルットの先端部は、導入目的部位の血管形状に合わせて、ほぼ同じ位置で湾曲しており、上記スタイルットの先端は、上記カテーテルの先端から突出していないことを特徴とするスタイルット付きカテーテル。

【0007】(2) 上記カテーテルは、先端から4～8cmの位置であり、かつ上記スタイルットとほぼ同じ位置で湾曲している第1の湾曲部と、該第1の湾曲部よりも先端側の位置で湾曲している第2の湾曲部とを備える上記(1)に記載のスタイルット付きカテーテル。

【0008】(3) 上記第1の湾曲部は、上記カテーテルの本体部を通る線と上記カテーテルの先端部のほぼ直線である第1の部分を通る線とのなす角θ₁が30～70度になるように形成されている上記(2)に記載のスタイルット付きカテーテル。

【0009】(4) 上記第2の湾曲部は、上記カテーテルの先端から1～3cmの位置で湾曲している上記(2)または(3)に記載のスタイルット付きカテーテル。

【0010】(5) 上記第2の湾曲部は、上記カテーテ

ルの先端部のほぼ直線である第1の部分を通る線と上記カテーテルの先端部のほぼ直線である第2の部分を通る線とのなす角θ₂が5～45度になるように形成されている上記(2)～(4)のいずれかに記載のスタイルット付きカテーテル。

【0011】(6) 上記カテーテルの第1の湾曲部よりも先端側は、上記カテーテルの本体部よりも剛性が低くなるように形成されている上記(2)～(5)のいずれかに記載のスタイルット付きカテーテル。

【0012】(7) 上記カテーテルは、先端部が上大静脈に留置される高カロリー輸液用静脈カテーテルである上記(1)～(6)のいずれかに記載のスタイルット付きカテーテル。

【0013】

【発明の実施の形態】本発明のスタイルット付きカテーテルは、先端部と本体部と基端部とからなる可撓性カテーテルと、該カテーテルの内腔に挿通された、先端部と本体部と基端部とからなるスタイルットとが、該カテーテルの基端部と該スタイルットの基端部とで係合されているスタイルット付きカテーテルであって、上記カテーテルの先端部および上記スタイルットの先端部が、導入目的部位の血管形状に合わせて、ほぼ同じ位置で湾曲または屈曲（以下、単に「湾曲」ともいう）しており、上記スタイルットの先端が、上記カテーテルの先端から突出していないことを特徴とするスタイルット付きカテーテルである。以下に、本発明のスタイルット付きカテーテルについて好適な1例を図面を用いて詳細に説明するが、本発明のスタイルット付きカテーテルはこれに限定されない。

【0014】図1の本発明のスタイルット付きカテーテルの全体側面図に示すように、カテーテル1は先端部3と本体部4と基端部5とから構成されおり、スタイルット2は、先端部300と本体部400と基端部500とから構成されている。ここで、先端部とは、図2および図3の本発明のスタイルット付きカテーテルの先端部の拡大図に示すように、カテーテル1とスタイルット2とが、ほぼ同じ位置で湾曲している第1の湾曲部31を含む第1の湾曲部31より先端側の湾曲している部分のことであり、本体部とは、カテーテル1およびスタイルット2の湾曲していない部分のことである。

【0015】また、基端部とは、図4の本発明のスタイルット付きカテーテルの基端部の拡大図に示すように、カテーテル1およびスタイルット2に付属物（カテーテルコネクタ51、スタイルットコネクタ52およびロック部53）が付いている部分および該付属物のことである。具体的には、上記基端部には、カテーテル1を固定できるカテーテルコネクタ51と、該カテーテルコネクタ51と嵌合可能であって、さらに、カテーテルコネクタ51の内腔に挿通しているスタイルット2を固定できるスタイルットコネクタ52とが備え付けられている。

また、上記スタイルコネクタ52はロック部53を有しており、該ロック部53のロック機構をもって、カテーテルコネクタ51とスタイルコネクタ52とをロック嵌合させることで、スタイルコネクタ52がカテーテルコネクタ51に確実に装着固定されている。したがって、上記基端部とは、雄ルアーが嵌合可能なカテーテルコネクタ51、スタイルコネクタ52およびロック部53、さらにカテーテル1の該カテーテルコネクタ51と接触している部分、およびスタイル2の該カテーテルコネクタ51の内腔に挿通してスタイルコネクタ52と接触している部分のことである。

【0016】また、上記スタイルコネクタ52は、スタイルコネクタ52の先端から後端までを連通した内腔を設け、該後端にシリンジ等を接続させることにより、液体（薬液）が通過可能となるように構成されている。これによりスタイル2をカテーテル1から抜かずに、カテーテル内の生理食塩水等によるプライミングや、血液の逆流を目視することによるカテーテルの先端33が血管内に入っているか、入っていないかの確認をすることが可能となる。

【0017】上記先端部における第1の湾曲部31は、カテーテルの先端部3とカテーテルの本体部4、およびスタイルの先端部300とスタイルの本体部400、がほぼ同じ位置で湾曲している湾曲部であって、カテーテルの先端33より4~8cmの範囲に形成されていることが好ましく、4.5~6cmの範囲に形成されていることがより好ましい。また、上記第1の湾曲部31は、カテーテルの本体部4を通る線とカテーテルの先端部3のほぼ直線である第1の部分を通る線とのなす角、およびスタイルの本体部400を通る線とスタイルの先端部3のほぼ直線である第1の部分を通る線とのなす角、すなわち図3に示すように、カテーテルの本体部4およびスタイルの本体部400を延長した破線と、第1の湾曲部31から第2の湾曲部32までの湾曲していない仮想直線を延長した破線とのなす角を角度θ₁とすると、角度θ₁が30~70度の範囲になるように形成されていることが好ましく、より好ましくは35~60度、さらには40~50度である。また、上記なす角の定義においては、図3に示される先端部は、第1の湾曲部31および第2の湾曲部32で直線的に曲げられた構造として説明しているが、本発明のカテーテルは、図2に示す先端部のように、湾曲部において湾曲した構造となっている。血管壁に当たった際に、血管壁を傷つけにくい理由から好ましい。

【0018】上記第1の湾曲部31の形成位置および角度θ₁を上記範囲内に形成されることによって、上述した迷入の原因となる鎖骨下静脈と内頸静脈の分岐点付近にカテーテルを穿刺する場合においても、図5および6に示すように、カニューラ10から突出したカテーテルの先端部付近は至適留置域以外の血管へ行かない形状と

なるため好ましい。したがって、カテーテルの先端部3およびスタイルの先端部300に第1の湾曲部31を形成させることによって、鎖骨下静脈と内頸静脈の分岐部付近よりも肩側の遠位からは勿論のこと、分岐部付近に穿刺してしまった場合においても確実に上大静脈の方向へカテーテルを挿入することが可能となる。

【0019】上記第1の湾曲部31の形成位置が上記範囲以外に形成されると、カテーテルの先端33が反対側の鎖骨下静脈へ迷入したりする可能性が生じる。また、上記角度θ₁が、30度未満の場合は、角度が小さすぎて、カテーテルの先端33が内頸静脈へ挿入されてしまう危険性があり、70度超の場合は、カテーテルの先端33が上大静脈へ挿入されたときに、カテーテルの先端33が血管壁に当たり易くなり、カテーテル挿入時において血管壁を傷つけてしまう可能性がある。

【0020】また、本発明のスタイル付きカテーテルの第1の湾曲部31における曲げ半径ρ₁は、3mm未満の場合は湾曲部が鋭くなり血管を刺激してしまう恐れがあり、50mm超の場合は湾曲になりすぎ上述したカテーテル挿入時の手元感覚がよく分からなくなる場合があるため、湾曲部における曲げ半径ρ₁は、3~50mmの範囲であることが好ましい。

【0021】さらに、先端部において、上記カテーテル1は、上記第1の湾曲部31よりカテーテルの先端33側の位置に、第2の湾曲部32が設けられている。すなわち、本発明のスタイル付きカテーテルは、カテーテルの先端部3において、第1の湾曲部31および第2の湾曲部32で湾曲した形状を有している。ここで、上記第2の湾曲部32は、カテーテルの先端33より1~3cmの範囲に形成されていることが好ましく、1.5~2.5cmの範囲に形成されていることがより好ましい。また、上記第2の湾曲部32は、カテーテルの先端部3のほぼ直線である第1の部分を通る線とカテーテルの先端部3のほぼ直線である第2の部分を通る線とのなす角、すなわち図3に示すように、第1の湾曲部31から第2の湾曲部32までの湾曲していない仮想直線を延長した破線と、第2の湾曲部32からカテーテルの先端33までの湾曲していない仮想直線を延長した破線とのなす角度を角度θ₂とすると、角度θ₂が5~45度の範囲であることが好ましく、より好ましくは7~40度、さらには10~30度である。また、上述したように、上記なす角の定義においては、図3に示される先端部は、第1の湾曲部31および第2の湾曲部32で直線的に曲げられた構造として説明しているが、本発明のカテーテルは、図2に示す先端部のように、湾曲部において湾曲した構造となっている。血管壁に当たった際に、血管壁を傷つけにくい理由から好ましい。

【0022】上記第2の湾曲部32の形成位置および角度θ₂を上記範囲内に形成させることによって、上大静脈への留置操作がより確実となるため好ましい。具体的

には、例えば、右鎖骨下静脈穿刺を行う際に、穿刺位置、穿刺角度、患者の体の大きさ等により、第1の湾曲部31がカニューラより突出した段階で、カテーテルの先端33が反対側の左鎖骨下静脈内に挿入されてしまうという可能性がなくなるため好ましい。また、カニューラの先端から突出した本発明のスタイルット付きカテーテルは、真っ直ぐなカテーテルや湾曲部を1つだけ有するカテーテルに比べ、血管壁と衝突する血管壁との角度が小さくなり、血管壁に対し突き当たる時の加重がより小さくなるため好ましい。

【0023】また、上述したように、スタイルット2は、スタイルットの先端部300において、第1の湾曲部31で角度θ₁に湾曲した形状を有しているが、スタイルットの先端34は、第2の湾曲部32よりもカテーテルの先端33側に位置していてもよく、上記カテーテル1と同様、第2の湾曲部32において角度θ₂で湾曲した形状を有していてもよい。カテーテル1およびスタイルット2が、ともに第1の湾曲部31および第2の湾曲部32を有している場合には、カテーテルの先端部3の形状が保持されやすくなり、カテーテル1の第1の湾曲部31と第2の湾曲部32との間に、スタイルットの*

$$\text{突き当て加重 [N]} = (\text{所定長スタイルットが挿入された時の加重 [N]}) - (\text{スタイルット未挿入時の加重 [N]}) \quad (1)$$

【0025】上記突き当て加重は、(株)島津製作所製万能試験機オートグラフAG-1を用い、所定の長さのスタイルットを挿入した真っ直ぐなカテーテルの先端より5cmのところを持ち、該カテーテルを押し込み速度100mm/minで垂直に移動させ、平面に突き当て、カテーテルが撓み始めた時点での加重の平均値(n=5)として求められる。16Gサイズのポリウレタン

30 【0026】

【表1】

表1

カテーテルの先端からの スタイルットの先端位置(mm)	0	2	5	10	20	30
突き当て加重(N)	0.90	0.60	0.48	0.33	0.26	0.25

【0027】表1に示す結果より、カテーテルの先端33からのスタイルットの先端34の位置が、2mmよりも小さい場合は、スタイルットが挿入されていないカテーテルの突き当て加重に比べ0.5N以上高くなってしまい、血管壁を強く刺激する可能性があることが分かる。一方、カテーテルの先端33からのスタイルットの先端34の位置が、5mm以上の場合は、スタイルットが挿入されていないカテーテルの突き当て加重と比較しても、該加重の差は0.5N以下となるため、血管壁への刺激は低く、血管壁を必要以上に刺激しないことが分かる。したがって、スタイルットの先端34の位置としては、スタイルットの先端34がカテーテルの先端33よりも5mm以降に位置することが好ましい。

【0028】また、スタイルットの先端34の位置は、カテーテル1に設けられた第1の湾曲部31よりも1c

* 先端34が位置する場合には、カテーテルの先端部3、特に、第2の湾曲部32よりも先端側の部分は柔軟性を有することになる。

【0024】本発明のスタイルット付きカテーテルは、カテーテル1の内腔に挿通するスタイルット2が、カテーテルの先端33から突出しない、すなわちスタイルットの先端34がカテーテルの先端33から突出しないよう備えられている。スタイルット付きカテーテルがこのような構造を有していれば、カテーテル挿入時において、血管への突き当て加重を低くすることができ、血管壁を傷つけないといった効果を有するため好ましい。上記突き当て加重の適正範囲としては、具体的には、例えば、高カロリー輸液療法として最もよく使われている16Gサイズのシングルルーメンカテーテルに0.025インチ(inch)のステンレス製スタイルット(本体部、先端部とも同一剛性)を挿入した場合においては、0.5N以下であることが好ましい。ここで、上記突き当て加重とは下記式(1)に示されるように、スタイルットが挿入されることによって発生する追加加重のことである。

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※ルーメン30cmに、0.025インチ(inch)のステンレス製スタイルット(スプリングタイプ、本体部先端部とも同一剛性)を挿入して形成するスタイルット付きカテーテルの場合におけるカテーテルの先端からのスタイルットの先端の位置と突き当て加重の関係を下記表1に示す。

20 【0026】

【表1】

表1

m以上先端側に位置することが、血管挿入時において、カテーテルの本体部が捻れることがなく、第1の湾曲部31で湾曲させたカテーテルの先端33の向きを確実に把握することができることから、術者は未熟な者であっても安心してカテーテルを挿入することが可能となるため好ましい。一方、スタイルットの先端34が第1の湾曲部31よりも本体部側に位置する場合、カテーテルの本体部4は捻れる可能性があり、カテーテルの先端33の向きを把握することができず、カテーテルの挿入操作に支障をきたす場合がある。また、スタイルットの先端34の位置が、第1の湾曲部31よりも先端側の1cm以内に位置する場合も同様で、スタイルットの先端34よりも先端側のカテーテルの形状を保持する能力に乏しくなる。以上より、スタイルットの先端34の至適位置範囲としては、カテーテルの先端33よりも5mm以降であ

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り、第1の湾曲部31よりも1cm以上先端側に位置していることが好ましい。

【0029】また、カテーテルの血管壁への突き当たる重を下げるよう、カテーテル1およびスタイルット2の第1の湾曲部31よりも先端側は、それぞれの本体部よりも剛性が低くなるように形成されていてもよい。具体的には、スタイルット2の構造が、スタイルットの先端34から第1の湾曲部31までの間において、剛性が低くなるように傾斜物性をもたせててもよい。一方、スタイルット2は、塑性変形しない範囲においては、変形に対しバネのような復元性を示すことが好ましい。具体的には、カテーテル挿入時において、カニューラからカテーテルが突出し始め、第1の湾曲部31がカニューラの先端を通過するまでの間は、カニューラの形状が真っ直ぐなため、30~70度(θ_1)に形成された第1の湾曲部31は比較的真っ直ぐになるように矯正されているが、第1の湾曲部31がカニューラの先端より突出した際には、第1の湾曲部31は、角度 θ_1 まで容易に復元する。術者はこの現象を手元の感覚で認識することができるため、例えば、カテーテルの先端33から5cmのところに第1の湾曲部31が形成されている場合は、カテーテルがカニューラの先端より5cm先に体内に入ったことを認識することが可能となる。従来のカテーテル、例えば、スタイルットが装着されていない真っ直ぐなカテーテルのような場合では、カニューラの全長とカテーテルに印刷されている深度マークとの位置関係からカテーテルの先端の位置を類推するしかなかったので、上述したような手元感覚は術者にカテーテルの先端33の位置の情報を的確に伝えることが可能となり非常に有効である。

【0030】また、本発明のスタイルット付きカテーテルにおいて、カテーテルの先端33の方向性を視認するためには、カテーテルコネクタ51やスタイルットコネクタ52にマークをつけておくことが好ましく、上記した深度マークを目印としてもよい。具体的には、スタイルットコネクタ52に、湾曲部における曲げ方向とは逆方向(図1では上側を指す)の矢印等のマークを印字、あるいは刻印し、カテーテル挿入時に必ず該マークが上を向くようにするとよい。このような構成をとることによって、カテーテルの先端33がマークとは必ず反対方向に向くようになり、容易に上大静脈へ挿入することができるため好ましい。

【0031】ここで、上述したカテーテルの材質としては、可撓性を有するものが好ましい。この様なものとしては、高分子エラストマーが好適に例示され、以下に示す理由から、熱可塑性ポリウレタンであることがより好ましい。熱可塑性ポリウレタンは、生体適合性および血液適合性が高く、比較的長期留置にも使用されている。また、高分子エラストマーは、所望の形状に変化させた後に、該高分子エラストマーのガラス転移温度以上の温

度で熱処理を施し、その形状のまま冷却することによって形状記憶性を発揮するため、適度に所望の形に形状を変化させることも可能であり、上記第1および第2の湾曲部についても所望の角度、曲率に形状を変化させることができるために好ましい。この様な高分子エラストマーの弾性率は、温度依存性を示し、一般的には高温にするほど柔軟化する。熱可塑性ポリウレタンのような場合は、さらに吸水性も有しているので、血管内に留置された後は体温と血液の両者によって柔軟化し、湾曲部を有する形状も徐々に緩和され、比較的真っ直ぐな状態になることができる。そのため、予めつけられた形状による血管壁への接触も特に問題とならないため好ましい。また、この様な材料を用いれば、特殊なコーティングを行うことで、カテーテルに、例えば抗血栓性付与、抗菌性付与することも可能である。

【0032】また、カテーテルの内腔に挿通されたスタイルットの材料としては、金属製、例えば、スプリングワイヤーや撚り線等のステンレススチール、NiTi合金、樹脂が被覆されたNiTi合金等の金属、および/または、ナイロン、ポリエチレン等の高弾性率の高分子材料を用いることが、非常に柔らかいカテーテルに対しても適度な剛性を与えることが可能となるため好ましい。

【0033】さらに、上記カテーテルおよびスタイルットの外表面を水溶性高分子、具体的には、ポリビニルピロリドン、メチルビニルエーテル無水マレイン酸ナトリウム、ポリアクリルアミド加水分解物、アルギン酸ナトリウム、ポリビニルスルホン酸ソーダ、メチルビニルエーテル無水マレイン酸のアンモニウム塩、ポリアクリルアミド四級化合物等で被覆し、水または水性溶液で濡らすことにより潤滑性を保持させるようにしてよい。例えば、ヘパリン加生理食塩水に浸したガーゼ等でカテーテルの表面を軽く拭くことにより、水溶性高分子を湿润させ、潤滑性を持たせることができる。

【0034】本発明のスタイルット付きカテーテルにおいて、カテーテルの内腔に挿通されたスタイルットは、従来のガイドワイヤの代用として作用し、血管内の所望部位へ容易に導入させることができるとなる。また、カテーテルの先端部およびスタイルットの先端部が、導入目的部位の血管形状に合わせて、ほぼ同じ位置で湾曲しており、スタイルットの先端が、カテーテルの先端から突出していることから、カテーテルを血管内に挿入していく際に、スタイルットの先端により血管壁を傷つける恐れがなく、未熟練の者でも安全、正確かつ容易に正しい位置(例えば上大静脈)にカテーテルを進入させることができるために好ましい。さらに、スタイルットの基端部に備え付けられているスタイルットコネクタは、上述したように薬剤等の液体が通過可能な内腔が設けられているため、該スタイルットコネクタをカテーテルコネクタに固定させれば、薬液をスタイルットコネクタの内腔を

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通してカテーテルの内腔に注入することができるので、プライミング操作や、血液を吸引しその逆流を視認することによるカテーテル血管留置の確認の際に、カテーテルからスタイルットを抜去する必要がないため好ましい。

【0035】

【実施例】本発明の一実施例に係るスタイルット付きカテーテルは、可撓性合成樹脂である熱可塑性ポリウレタン（ポリカーボネート系ポリウレタン、ショアー硬度98A）からなる外径 ϕ 1.5mm、内径 ϕ 1.0mm、カテーテル有効長300mmのチューブ状のカテーテルと、該カテーテルの基礎部に固定されたポリプロピレン樹脂製のカテーテルコネクタと、該カテーテルコネクタの内腔の中心部に、一端が固定され他端がカテーテルの内腔を挿通させてカテーテルの先端手前2cmで終わるように設けられた、外形 ϕ 0.6mmのステンレス製スプリングワイヤからなるスタイルットと、該スタイルットの基礎部に固定されたポリプロピレン製のスタイルットコネクタとからなっている。また、該スタイルット付きカテーテルは、高カロリー輸液療法に用いるため、上大静脈に留置させやすいように湾曲部を2個所有しており、第1の湾曲部は、カテーテルの先端より5cmの位置で、第2の湾曲部は、カテーテルの先端より2cmの位置にある。さらに、上記湾曲部における湾曲の角度は、上記第1の湾曲部における θ_1 は45度であり、上記第2の湾曲部における θ_2 は15度である。

【0036】

【発明の効果】本発明のスタイルット付きカテーテルは、カテーテルの先端部の湾曲形状および向きが確実に維持され、挿入時の方向確認を行えばどの穿刺位置においても必ず上大静脈の方向へカテーテルが挿入されるため、未熟な術者においても、上大静脈以外の血管への迷入させることなく、容易に安心感を持ってカテーテル留置操作を行うことができるため有用である。

【図面の簡単な説明】

【図1】 本発明のスタイルット付きカテーテルの全体側面図である。

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* 【図2】 本発明のスタイルット付きカテーテルの先端部の拡大図である。

【図3】 本発明のスタイルット付きカテーテルの先端部の拡大図である。

【図4】 本発明のスタイルット付きカテーテルの基礎部の拡大図である。

【図5】 本発明のスタイルット付きカテーテルの第1の湾曲部がカニューラより突出しているときの概略図である。

10 【図6】 本発明のスタイルット付きカテーテルを図5に示す状態からさらに奥に挿入したときの概略図である。

【図7】 患者が正面を向いている時の上大静脈（中心静脈）付近の血管の概略図である。

【図8】 患者が左方向を向いている時の上大静脈（中心静脈）付近の血管の概略図である。

【図9】 従来のスタイルット付きカテーテルの全体図である。

20 【図10】 従来のスタイルット付きカテーテルがカニューラより突出しているときの概略図である。

【符号の説明】

- 1 カテーテル
- 2 スタイレット
- 3 カテーテルの先端部
- 4 カテーテルの本体部
- 5 カテーテルの基礎部

10 カニューラ

31 第1の湾曲部

32 第2の湾曲部

30 33 カテーテルの先端

34 スタイレットの先端

51 カテーテルコネクタ

52 スタイレットコネクタ

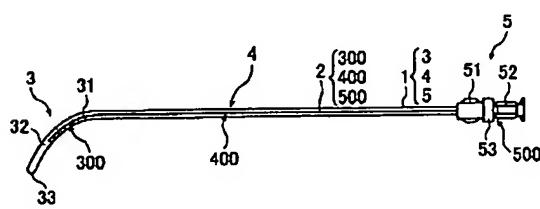
53 ロック部

300 スタイレットの先端部

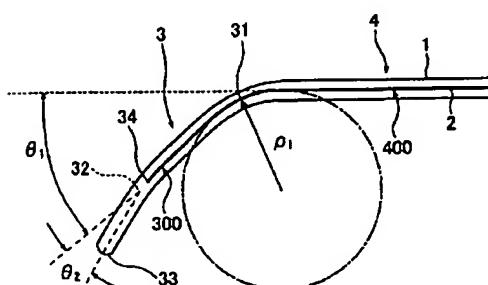
400 スタイレットの本体部

500 スタイレットの基礎部

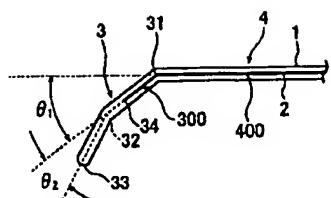
【図1】



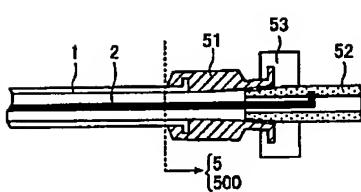
【図2】



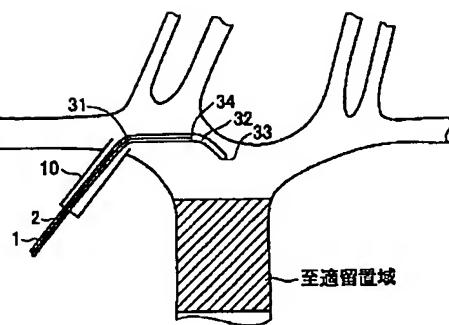
【図3】



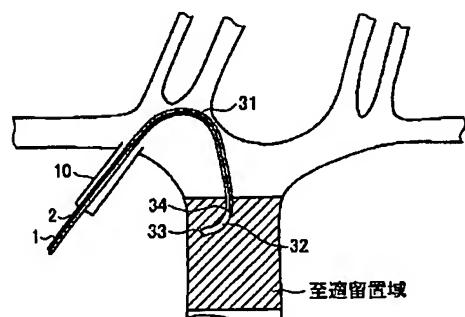
【図4】



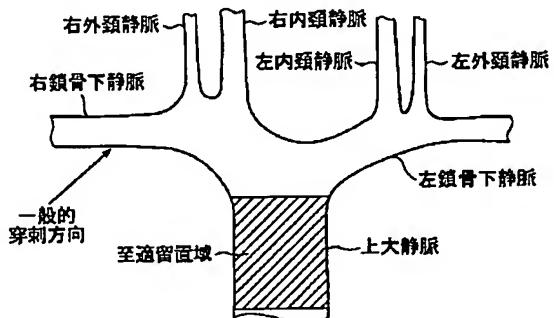
【図5】



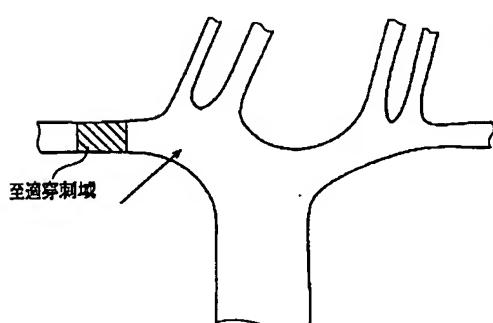
【図6】



【図7】



【図8】



【図9】



【図10】

